

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 06 JUN 2005

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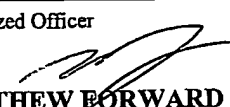
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Applicant's or agent's file reference 12846PC2-MLE/AKB	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2005/000106	International filing date (day/month/year) 28 January 2005	Priority date (day/month/year) 28 January 2004
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61M 5/315		
Applicant UNITRACT SYRINGE PTY LTD et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

Date of submission of the demand 14 April 2005	Date of completion of the report 19 May 2005
Name and mailing address of the IPBA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  MATTHEW FORWARD Telephone No. (02) 6283 2606

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2005/000106

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1 (b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
 - ☐ the international application as originally filed/furnished
 - ☒ the description:
 - pages **1 to 6** as originally filed/furnished
 - pages* received by this Authority on with the letter of
 - pages* received by this Authority on with the letter of
 - ☒ the claims:
 - pages as originally filed/furnished
 - pages* as amended (together with any statement) under Article 19
 - pages* **7, 8** received by this Authority on **14 April 2005** with the letter of **14 April 2005**
 - pages* received by this Authority on with the letter of
 - ☒ the drawings:
 - pages **1/6 to 6/6** as originally filed/furnished
 - pages* received by this Authority on with the letter of
 - pages* received by this Authority on with the letter of
 - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2005/000106

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1 to 16	YES
	Claims	NO
Inventive step (IS)	Claims 1 to 16	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 to 16	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 US 4642102 (OHMORI)
- D2 GB 2203047 (BANKS et al)
- D3 WO 1989012476 (FAVARD)
- D4 ES 2031756 (GUTIERREZ DE CEPEDA)
- D5 WO 1994013339 (MALLINCKRODT MEDICAL, INC.)
- D6 US 5328476 (BIDWELL)
- D7 US 20010049506 (SCHOENFELD et al)

The amended claims define a pawl on the outer member of a collar mechanism mounted in the barrel of the syringe. The collar also has an inner member that prevents the pawls from engaging the ratchet until the plunger is depressed.

Document D1 recites a syringe having a plunger (2) with a stopper mechanism (3) that abuts against the barrel of the syringe and prevents the plunger from being advanced beyond a certain length. The object is to produce a more accurate injection compared to a graduated syringe.

D2 provides a syringe having a plunger with splines to prevent rotation of the plunger and ratchet teeth (28) engage with pawl (29) on the separate end plate (5). Teeth (28) and pawl (29) cooperate to prevent the plunger from being withdrawn once the injection stroke is commenced. In addition ratchet teeth (15) and pawl (16) on an opposite side of the plunger prevent the injection during the fluid drawing process.

D3 is directed to a syringe with a double pawl mechanism mounted on a separate collar (figure 1). The pawls engage with serrations on the plunger (figure 3) to block movement of the plunger back from the injection stroke.

In Document D4, the plunger has two sets of serrations (A, B) arranged in opposite directions to each other. A mechanism (M) prevents the plunger from moving in one of the directions. A different mechanism prevents serrations A from being used twice.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Document D5 is directed to mechanisms preventing rearward movement of a plunger using ratchet on the plunger and detent (60) mounted to flexible insert (57). Insert also includes an alignment member (59) (see figure 2). D5 includes a further embodiment (figure 11), wherein two ratchet portions are mounted to the interior of the housing and two detent portions are mounted on the plunger.

D6 provides a plunger with two sets of grooves (24, 26) and two pawls (34) facing in opposite directions.

D7 is directed to a simple ratchet on the plunger and separate pawl mechanism to prevent reuse of a syringe.

None of documents D1 to D7 disclose the arrangements as defined in independent claims 1 and 15.

Claims 1 to 16 are considered to satisfy Articles 33(2) to 33(4) of the PCT. They are novel and possess an inventive step in view of the cited documents and have a self evident industrial application.

CLAIMS

1. A disabling system for a syringe, said disabling system comprising a plunger having at least one ratchet and a collar mountable to a barrel of said syringe, said collar comprising an inner member and an outer member having at least one pawl
5 capable engaging said ratchet, said inner member operable to prevent engagement of said ratchet by said at least one pawl until said plunger is depressed.
2. The disabling system of Claim 1, wherein the plunger comprises two opposed ratchets, each disposed longitudinally along said plunger.
3. The disabling system of Claim 2, wherein each of said two opposed ratchets
10 are alignable relative to two pawls so as to be capable of engaging said two pawls to prevent withdrawal of said plunger during or following depression of said plunger.
4. The disabling system of Claim 3, wherein each of said two opposed ratchets comprise a plurality of aligned steps, teeth or abutments.
5. The disabling system of Claim 1, wherein the inner member and the outer
15 member are in use incapable of rotation relative to each other.
6. The disabling system of Claim 5, wherein said outer member comprises two fingers capable of slidably engaging respective, opposed guide slots located on said plunger to thereby prevent rotation of said plunger relative to said collar.
7. A syringe comprising a plunger comprising at least one ratchet, a barrel and a
20 collar mountable to said barrel, said collar comprising an inner member and an outer member having at least one pawl, said inner member operable to prevent engagement of said ratchet by said at least one pawl until said plunger is depressed.
8. The syringe of Claim 7, wherein the collar comprises two pawls.
9. The syringe of Claim 8, wherein the plunger comprises two opposed ratchets,
25 each disposed longitudinally along said plunger.
10. The syringe of Claim 9, wherein said two opposed ratchets are respectively alignable with the two pawls so as to be capable of respectively engaging said pawls, in use to prevent withdrawal of said plunger during or following depression of said plunger.
- 30 11. The syringe of Claim 10, wherein each of said two opposed ratchets comprise a plurality of aligned steps, teeth or abutments.

12. The syringe of Claim 7, wherein said collar comprises an inner member and an outer member having said two pawls capable of engaging said ratchet to prevent withdrawal of said plunger during depression of said plunger. 13. The syringe of Claim 12, wherein the inner member and the outer member are incapable of rotation
5 relative to each other.

14. The syringe of Claim 13, wherein said outer member comprises two fingers that slidably engage respective, opposed guide slots located on said plunger to thereby prevent rotation of said plunger relative to said collar.

15. A syringe comprising:

- 10 (i) a barrel that comprises two pawls; and
(ii) a plunger comprising:
(c) two opposed ratchets respectively engageable by said two pawls to prevent withdrawal of said plunger during or following depression of said plunger; and
15 (d) two opposed guide slots;

wherein said barrel comprises a collar having an inner member and an outer member that are incapable of rotation relative to each other, said inner member operable to prevent engagement of said ratchet by said two pawls until said plunger is depressed, said outer member comprising said two pawls and further comprising two
20 fingers that respectively slidably engage said opposed guide slots of said plunger to thereby prevent rotation of said plunger relative to said collar.

16. A method of operating the syringe of Claim 7, said method including the step of depressing said plunger from a first position at which said at least one pawl is not engageable with said plunger to a second position at which said at least one pawl is
25 engageable with said plunger and thereby prevents withdrawal of said plunger.